REMARKS

Claims 1, 3-16, 21 and 23 are currently pending in this application. Claims 17-20 and 22 have been canceled. Claims 1, 12, 15, 16 and 21 have been amended. No new matter has been added by these amendments. Applicants have carefully reviewed the Advisory Action and respectfully request reconsideration of the claims in view of the remarks presented below.

Election/Restrictions

Claims 1, 3-16, 21 and 23 were identified as being drawn to a device for detecting ischemia based on T-wave slope and energy value while claims 17-20 and 22 were identified as being drawn to a device/method for detecting ischemia based on total T-wave energy. Based on a telephonic provisional election, claims 17-20 and 22 were withdrawn from further consideration as being drawn to a non-elected invention. Applicants affirm their provisional invention election and accordingly, have canceled claims 17-20 and 22.

Claim Rejections Under 35 U.S.C. §112

Claim 21 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the phrase "their respective threshold" was cited as lacking antecedent basis.

Claim 21 has been amended to provide antecedent basis for the phrase "their respective threshold."

Claim Rejections Under 35 U.S.C. §103

Claims 1, 3, 5-8, 10-16, 21 and 23 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,823,213 (Norris) in view of U.S. Patent No. 5,792,065 (Xue).

Independent claim 1 relates to a method that detects cardiac ischemia, on a T-wave by T-wave basis, through an analysis of individual T-wave characteristics. To this end, claim 1 recites detecting a plurality of individual T-waves within cardiac signals; determining an energy value for each of the plurality of individual T-waves; and calculating a plurality of slopes for each of the plurality of individual T-waves. Claim 1 further recites, for each of the plurality of individual T-waves, determining the maximum slope from the plurality of slopes and comparing the maximum slope to a threshold maximum slope and the energy value to a threshold energy value; and for each of the plurality of individual T-waves, detecting cardiac ischemia when the energy value and the maximum slope of the T-wave exceeds its respective threshold.

Independent claim 21 relates to a system that provides for the detection of cardiac ischemia in a manner similar to that recited in method claim 1.

Norris discloses a device related to the detection and analysis of T-wave alternans as a means of identifying patients at risk for sudden cardiac death. Column 1, lines 9-10. By way of background, T-wave alternans refers to an alternation in the morphology of a T-wave in an AB-AB pattern, wherein the A-morphology may correspond to even heart beats and the B-morphology to odd heart beats. See column 1, lines 32-33; column 13, lines 39-41; column 14, lines 11-12 and figure 9A. Because the Norris device is alternans based, it necessitates the collection and processing of ECG data over two or more alternating heartbeats in order to perform its intended function, *i.e.*, to detect an alternation between successive beats. Column 13, lines 39-41. Even heartbeat data and odd heartbeat data are separately collected and processed. See figure 10, blocks 150 and 154. This data is subsequently processed together and then compared to a threshold to determine if T-wave alternans is detected. See figure 10, blocks 156, 158 and 170. Norris does not teach or suggest – nor, because of the pattern recognition nature of alternans analysis, would it be expected to teach or suggest – the detection of T-wave alternans using an individual T-wave.

Xue teaches a method for determining T-wave marker points. It is cited for its disclosure of a maximum slope (MSP) of a T-wave. See figure 7. On this matter,

Applicants note: 1) Xue's MSP is merely a point on the T-wave; it does not define a slope and 2) Xue does not describe how the MSP was determined. Therefore, Xue cannot be reasonably interpreted as teaching calculating a plurality of slopes for each of a plurality of individual T-waves; and for each of the plurality of individual T-waves, determining the maximum slope from the plurality of slopes, as recited in Applicants claims. Furthermore, if the Examiner is interpreting the various points on the graph of figure 7 as defining a plurality of slopes – despite the absence of any such teaching by Xue – Applicants submit that Xue still fails to disclose determining a maximum slope from a plurality of slopes. This is evident from figure 7, wherein the actual maximum slope of the T-wave is clearly defined by two points (38 and 40) – neither of which is Xue's maximum slope.

In view of the foregoing, Applicant submits that neither Norris nor Xue, either alone or in combination, teach or suggest the combination of elements and features recited in independent claims 1 and 21, including at least, determining a maximum slope of a T-wave from a plurality of slopes, and for each of the plurality of individual T-waves, detecting cardiac ischemia when the energy value and the maximum slope of the T-wave exceeds its respective threshold (claim 1) and means for determining a maximum slope for each of a plurality of T-waves from a plurality of slopes associated with the T-wave and means for detecting, for each T-wave, cardiac ischemia when the energy value and the maximum slope of the T-wave exceeds its respective threshold (claim 21). Accordingly, Applicant requests reconsideration of the §103 rejections of claims 1 and 21.

Applicants further submit that, in view of their incorporation of subject matter recited in their respective independent base claim, each of dependent claims 3, 5-8, 10-16 and 23 is also nonobvious over Norris and Xue. Aside from the foregoing, Applicants believe that dependent claims recite additional novel and/or nonobvious subject matter. For example, regarding claim 16, the Examiner has not cited any prior art disclosing the claimed features related to the generation of an ischemia warning signal having a stimulation frequency different from an arrhythmia warning signal. Prior Office Actions cited U.S. Patent 6,381,493 (Stadler) as disclosing this feature.

Applicants have reviewed Stadler (and other art of record) and note that the use of warning signals of different frequencies – one for ischemia and the other for arrhythmias, is not disclosed. Accordingly, Applicants traverse the statement by the Examiner presented in the Office Action, that it is well known in the art to generate warning signals that are different from other warning signals, and request the Examiner produce authority to support this statement.

Claim 4 was rejected under 35 U.S.C. §103(a) as being unpatentable over Norris in view of Xue and further in view of U.S. Patent Publication 2002/015807 (Goldin). Claim 9 was rejected under 35 U.S.C. §103(a) as being unpatentable over Norris in view of Xue and further in view of U.S. Patent Publication 2003/0060724 (Thiagarajan).

In view of the foregoing analysis of independent claim 1 in view of Norris and Xue, Applicants believe that the rejections under §103 are moot as dependent claims 4 and 9 depend from an allowable independent claim.

CONCLUSION

Applicants have made an earnest and bona fide effort to clarify the issues before the Examiner and to place this case in condition for allowance. Therefore, allowance of Applicants' claims 1, 3-16, 21 and 23 is believed to be in order.

Respectfully submitted,

11 OCT 2006
Date

David S. Sarisky, Reg. No. 41,288
Attorney for Applicant
818-493-3369

CUSTOMER NUMBER: 36802